

## REMARKS

### I. Examiner's Response to Arguments

Applicants acknowledge the Examiner's indication that objection to the drawings for failing to show at least claims 13-15, 38 and 39 has been withdrawn.

### II. Claim Rejections - 35 U.S.C. §112, first and second paragraphs

Reconsideration is requested of the Examiner's rejection of Claims 13-15, 38 and 39 under 35 U.S.C. 112, first and second paragraphs, as failing to comply with the enablement requirement and as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.<sup>1</sup> In particular, the Examiner indicated that "the additional stabilized assembly stabilizes the plates but does not stabilize the flexible supporting means."

As shown in Fig. 11A, the additional stabilizing assembly stabilizes either the upper or lower plates. The additional stabilizing assembly of Claim 13 is a distinct stabilizing means from the temporary stabilizing means of Claim 1. Claim 13 is amended accordingly such that the additional stabilizing assembly supports one of the two plates. Therefore, this rejection is believed to be moot.

Similarly, Claims 14, 15, 38 and 39 are dependent upon amended Claim 13, this rejection is also believed to be moot as to these claims.

### III. 35 U.S.C. §102 (Gauchet)

Reconsideration is requested of the Examiner's rejection of Claims 1-7, and 43-45 under 35 U.S.C. 102(e) as being anticipated by Gauchet et al., U.S. Patent No. 6,733,532. The

---

<sup>1</sup> The Examiner still refers the "additional stabilizing assembly" as a "supplemental support." Office Action, p.2. Applicants believe this issue has been fully addressed in the prior Amendment by changing all references of a supplemental support to an additional stabilizing assembly.

Examiner relied on the Gauchet reference for disclosing all the elements of Claim 1 and noted that the limitation “temporarily” of the stabilizing means was deleted from the claims.

A claim is anticipated under 35 U.S.C. §102(e) only if “**each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Amended Claim 1 discloses an artificial disc for placement between adjacent vertebrae comprising:

at least one upper substantially flat plate member and one lower substantially flat plate member, each plate member having corresponding outer and inner bearing surfaces;

at least one flexible supporting means interposed between said upper and lower plate members and abutting said corresponding inner bearing surfaces, said flexible support means flexibly and compressibly supporting said upper and lower plate members to allow compression of the adjacent vertebrae; and

***at least one means for temporarily stabilizing said flexible supporting means for a certain period of time*** to allow at least two of said outer bearing surfaces to osteo-integrate with the adjacent vertebrae, wherein ***said at least one temporarily stabilizing means allows limited axial rotation of said upper and lower substantially flat plate members***.

The Gauchet reference fails to teach, disclose or suggest, at least, the elements shown above in ***bold and italics***. The stabilizing means (12 or 22) relied on by the Examiner in the Gauchet reference is not temporary and does not allow limited axial rotation. Further, The Examiner appeared to rely on the lack of the limitation “temporarily” in relying on the Gauchet reference in rejecting the Claims. Applicants note that they previously took out the term “temporarily” because the limitations that follows, i.e. “means for stabilizing ... for a certain period of time ...,” have the same meaning as the term “temporarily.” However, in view of the Examiner’s reliance, the redundant term “temporarily” is now added back to Claims 1, 11, 12, and 24. Therefore, the Gauchet reference fails to teach “each and every element” of amended claim 1 and all claims dependent therefrom, as required under a §102(e) rejection.

Further, Applicants again submit that the Gauchet reference is not a proper prior art under a 35 U.S.C. 102(e) rejection. The Examiner apparently did not consider this position previously because the Examiner did not address Applicants' position. As correctly noted by the Examiner, the date of the Gauchet reference is governed by pre-AIPA law, which Applicants also relied on in their previous arguments.

As noted in M.P.E.P. §706.02(a) (emphasis added):

Patents issued directly, or indirectly, from international applications filed before November 29, 2000 may only be used as prior art based on the provisions of 35 U.S.C. 102(e) in effect before November 29, 2000. Thus, **the 35 U.S.C. 102(e) date of such a prior art patent is the earliest of the date of compliance with 35 U.S.C. 371(c)(1), (2) and (4), or the filing date of the later-filed U.S. continuing application** that claimed the benefit of the international application.

As shown on the face of the Gauchet reference, the 35 U.S.C. 371(c)(1), (2) and (4) date or filing date is **July 20, 2001**. On the other hand, the critical date of the present invention is **July 26, 1999**, based on the following priority: the present invention is a division of Serial No. 10/072,163, filed February 7, 2002 (now issued as U.S. Patent No. 6,719,796), which is a continuation of Serial No. 09/360,796, filed July 26, 1999 (now issued as U.S. Patent No. 6,454,806). Therefore, the Gauchet reference with a §102(e) date of July 20, 2001, cannot be cited as a prior art reference to the present invention with a priority date of July 26, 1999, under a §102(e) rejection.

#### IV. 35 U.S.C. §103 (Cauthen and Zdeblick)

Reconsideration is requested of the Examiner's rejection of Claims 1-5, 11-13 and 43-45 under 35 U.S.C. 103(a) as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, and Zdeblick et al., U.S. Patent No. 6,881,228. The Examiner relied on the Cauthen reference as

disclosing all the elements of the claims except for a substantially flat plate and relied on the Zdeblick reference for disclosing this element.

To clarify the present invention and its difference from the prior art cited by the Examiner, Applicants respectfully direct the Examiner to the history of artificial disks. All prior art artificial disks are divided into two distinct and opposing groups:

1. Artificial disk that allow only axial compression to absorb forces placed on the spine by acting as a shock absorber. Examples of this group of artificial disk includes:

- U.S. Patent No. 4,911,718 (Lee et al.)
- U.S. Patent No. 5,002,576 (Fuhrmann et al.)
- U.S. Patent No. 5,071,437 (Steffee)
- U.S. Patent No. 5,314,477 (Marnay)
- U.S. Patent No. 5,458,643 (Oka)
- U.S. Patent No. 5,593,409 (Michelson)
- U.S. Patent No. 5,609,635 (Michelson)
- U.S. Patent No. 5,674,294 (Bainville et al.)
- U.S. Patent No. 5,776,199 (Michelson)
- U.S. Patent No. 5,785,710 (Michelson)
- U.S. Patent No. 5,824,094 (Serhan)
- U.S. Patent No. 5,928,284 (Mehdizadeh)
- U.S. Patent No. 6,136,031 (Middleton)
- U.S. Patent No. 6,162,252 (Kuras et al.)
- U.S. Patent No. 6,733,532 (Gauchet)
- U.S. Patent No. 6,881,228 (Zdeblick et al.)

2. Artificial disk that resists and has no axial compression but provide for unrestrained axial rotation, flexion, extension, and in some instances translation in relation to the adjacent spinal segments. These devices are usually articulated in a ball and socket configuration. Examples of this group of artificial disk includes:

- U.S. Patent No. 5,258,031 (Salib et al.)
- U.S. Patent No. 5,425,773 (Boyd et al.)
- U.S. Patent No. 5,593,445 (Waits)
- U.S. Patent No. 5,676,701 (Yuan)

U.S. Patent No. 5,683,465 (Shinn)  
U.S. Patent No. 5,782,832 (Larsen)  
U.S. Patent No. 6,019,792 (Cauthen)  
U.S. Patent No. 6,368,350 (Erickson)

Typical of Group 2 prior art artificial disks is a bearing between the upper and lower portions that minimize the amount of seizing which may occur during the movement of the articulating surfaces. See, Erickson, col. 5, lines 63-65.

Material of a high durometer that is substantially resistant to axial compression is necessary to reduce the incidence of creating debris and to minimize the amount of seizing which may occur during the movement of the articulating surfaces by the weight of the patient into which the device is inserted. Id. col. 9, line 66 – col. 10, line 1; Waits, col. 5, line 66 – col. 6, line 19.

The present invention belongs to a third new group of artificial disk that allows axial compression along with restrained axial rotation, flexion and extension so as to act like a shock absorber and synergistically provides translation of the osteo-integrated vertebral endplates. Applicants are not aware of any prior art that belongs in this third group. This new group of artificial disk does not merely combine the two prior art groups because each prior art group teaches against what the other group teaches. Further, even assuming the two prior art groups are combinable, the combination results in axial compression with unrestrained axial rotation, which is patentably different from the axial compression with restrained axial rotation of the present invention. Applicants believe this new group of artificial disk provides the best result and a substantial advance from the prior art. The artificial disk of the present invention allows axial compression (flexible supporting means) but limited axial rotation (both the temporarily

stabilizing means and the compressive forces applied to the flexible supporting means through the upper and lower plate members that restrict such axial rotation).

The Examiner improperly relied on the wedges 82 and 94 of the Cauthen reference as the temporarily stabilizing means of the present invention because the wedges 82 and 94 are in constant contact with the endplates to restrict all axial rotation while the temporarily stabilizing means is present. Col. 6, line 43 – Col. 7, line 30. On the other hand, the temporarily stabilizing means of the present invention is not in constant contact with the upper and lower plate members but allows limited axial rotation of the plate members while the temporarily stabilizing means is present. See, Figure 16 (gap between the temporarily stabilizing means and the upper and lower plate members) and Claim 1. Therefore, the Cauthen reference does not disclose, teach or suggest, at least, the temporarily stabilizing means of amended Claim 1.

Similarly, the Zdeblick reference fails to teach, disclose or suggest the element lacking in the Cauthen reference, i.e. a temporarily stabilizing means that allows limited axial rotation of the plate members. Therefore, amended Claim 1, and all claims dependent therefrom, are not unpatentable over the Cauthen reference in view of the Zdeblick reference.

#### V. 35 U.S.C. §103 (Cauthen, Zdeblick and Shinn)

Reconsideration is requested of the Examiner's rejection of Claims 24, 14-15, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, and Zdeblick et al., U.S. Patent No. 6,881,228, and further in view of Shinn et al., U.S. Patent No. 5,683,465. The Examiner relied on the Cauthen and Zdeblick references as disclosing all the elements of the claims except for a "substance with anti-microbial drug eluting factors" and relied on the Shinn reference as disclosing such element.

As set forth in §IV, supra, it is improper to combine the Cauthen and Zdeblick references. Further, even if combinable, the Cauthen and Zdeblick references fail to teach, disclose or suggest a temporarily stabilizing means that allows limited axial rotation of the plate members. Similarly, the Shinn reference fails to teach, disclose or suggest a temporarily stabilizing means that allows limited axial rotation of the plate members. Therefore, amended Claims 1 and 24, and all claims dependent therefrom, are not unpatentable over the Cauthen and Zdeblick references in view of the Shinn reference.

#### VI. 35 U.S.C. §103 (Gauchet and Shinn)

Reconsideration is requested of the Examiner's rejection of Claim 24 under 35 U.S.C. 103(a) as being unpatentable over Gauchet, U.S. Patent No. 6,733,532, in view of Shinn et al., U.S. Patent No. 5,683,465. The Examiner relied on the Gauchet reference as disclosing all the elements of the claim except for a "substance with anti-microbial drug eluting factors" and relied on the Shinn reference as disclosing such element.

As set forth in §IV, supra, the Gauchet and Shinn references belong in the two opposing groups of prior art and are not combinable. Further, as set forth in §III, supra, the Gauchet reference is not a proper prior art reference under 35 U.S.C. 102(e) and also fails to teach, disclose or suggest a temporarily stabilizing means that allows limited axial rotation of the plate members. Similarly, the Shinn reference fails to teach, disclose or suggest a temporarily stabilizing means that allows limited axial rotation of the plate members. Therefore, amended Claim 24 is not unpatentable over the Gauchet reference in view of the Shinn reference.

#### VII. Allowable Subject Matter

Applicants acknowledge the Examiner's indication that Claims 17-20 are allowable if rewritten in independent form including all of the limitations of the base claim and any

intervening claims. Applicants reserve amending Claims 17-20 to independent form in view of the arguments presented above which Applicants believe overcome all outstanding rejections and objections.

#### VIII. New Claim

New Claim 46 is added to clarify the scope of the present invention. The subject matter of Claim 46 was previously claimed in Claims 14 and 15 and also disclosed in the Specification:

p.8, lines 18-21: "In certain situations of trauma and disease additional stabilization is required and a resorbable biocompatible photo-initiated polymer rod or plate and screws may be utilized and to be attached to the vertebrae involved as well as healthy vertebrae above and below the damaged site."

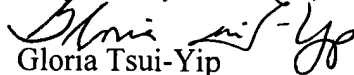
p.18, lines 14-16: "The clamping plate 36 is to be screwed or otherwise mounted to the central vertebrae 32 by a screw or some other suitable means 40."

Therefore, new claim 46 does not introduce any new matter.

#### IX. Conclusion

By virtue of the Applicants' amendment to the claims and remarks thereto, all outstanding grounds of rejection and objection have been addressed and dealt with and, based thereon, it is believed that the application is now in condition for allowance and such action is respectfully solicited.

Respectfully submitted,

  
Gloria Tsui-Yip

Attorney for Applicants

Reg. No. 42,188

STOLL, MISKIN & BADIE

350 Fifth Avenue, Suite 4710

New York, NY 10118

(212) 268-0900